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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/717,684

11/20/2003

Hai H. Tricu

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

05/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/717,684

Applicant(s)

TRIEU, HAI H.

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 28, 28, 31, 32 and 35-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6-27, 29, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/20/03; 7/20/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, method of intervertebral stabilization, species 1 of the patentably distinct systems, posterior approach, and device positioning shown in 3A in the reply filed on 2/12/07 is acknowledged. The traversal is on the ground(s) that prosecution of all patentable distinct subject matter does not burden the Examiner. This is not found persuasive because the search for each group and/or species requires a different search technique for the patentably distinct subject matter. Furthermore, execution of a search encompassing the entirety of applicant's device and method would not only constitute an undue burden on the Examiner, but consideration of the findings of such a search in accordance with the requirements of the law under 35 U.S.C. §§101, 102, 103 and 112 would be unduly onerous.

Moreover, it is further noted that a comprehensive search for the presently claimed subject matter is not solely limited to a search of the classes and subclasses in which they are classified. Therefore, it is obvious that a comprehensive search of the copious amounts of patent and non-patent literature for each of the patentably distinct inventions and their permutations presently claimed would necessarily place an undue burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-5, 31, 32 and 35-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and/or group as indicated by applicant.

Additionally, claims 28 and 29 are withdrawn by the Examiner being drawn to a nonelected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 34, "degrading the load support element" is not understood.

Please direct to the specification regarding the elected embodiment for support.

Claim 19, with respect to the elected embodiment, what does the last two lines mean? It is the Examiner's position that this claim should be withdrawn.

Claim 20, why is bone filler put in the expandable element when the expandable element is being removed?

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

All claim are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1, how does the elected expandable device preserve motion?

Claim 19, how does the elected embodiment maintain disc space after removing the expandable element? This is exactly opposite from claim 1. Further restriction may be necessary following an explanation.

As far as the scope of the claims can be determined, the following is made of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 6-13, 16-25, 30, 33, 34 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bao et al (7,077,865).

Refer to at least figure 14 which is supported in parent application 09/649491 filed 8/28/00. It is noted that most of the claims do not require a first or second portion (elements 34 and 44), therefore, applicant should consider all embodiments including figure 5 and/or wherein the first and second portions can simply be the upper and lower surfaces of the balloon, coatings, or elements 162 shown in figure 12, etc.

A method for intervertebral stabilization, comprising:

- accessing a disc space between vertebral bodies;

- delivering an expandable device (mold) into the disc space in an unexpanded condition;

- expanding the expandable device with an expandable element to-distract the disc-space (see at least 35:2 et seq. and claim 8);

- and placing a motion preserving device (biomaterial) in a cavity of the expanded expandable device. Regarding "motion preserving" the implants are disc replacements which preserve motion and not fuse the vertebrae together; see at least 24:17 et seq.

Claim 2, posterior approach, see at least figure 2.

Claim 11, first and second portions, see elements 182.

Claim 13, see elements 13.

Claim 18, removing the support is interpreted as degrading it. Also, the materials are biodegradable.

Claim 19, see at least 35:11 et seq. teaching pre-distract by other elements can be done which are removed.

All other claims are self-evident to one skill in the art.

Claims 1, 2, 6-27, 30, 33, 34 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Teitelbaum et al (6,582,467).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 15, 26, and 27 are rejected under 35 U.S.C. 102(e) as anticipated by
or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bao et al (7,077,865).

Boa et al teaches the method as described above including the prosthesis restores the desired anatomy and function of the disc and the method provides the option to reconstruct the disc in a manner that more closely approximates the

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relationship of the original annulus and nucleus. In restoring the relationship to a natural state, some adjacent vertebrae naturally have a greater anterior height, therefore, the implant would conform to this natural state.

under 35 U.S.C. 103(a):

It is well known in the art (such as Erickson 6,419,705) that some adjacent vertebrae naturally have a greater anterior height and would have been obvious to one having ordinary skill in the art to make the prosthesis of Boa et al accordingly to restore the adjacent vertebrae to their natural spacing/disc space.

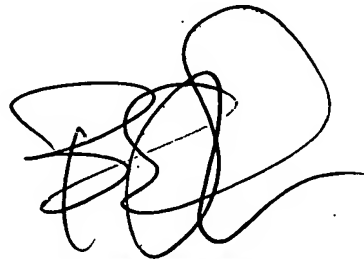
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

bes

A handwritten signature in black ink, appearing to read 'BSN', with a large, loopy flourish extending from the right side.

BRUCE SNOW
PRIMARY EXAMINER